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November 1, 2018

VIA ECF

Honorable Judge Claire C. Cecchi
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

In Re: Proton-Pump Inhibitor Products Liability Litigation
2:17-md-2789 (CCC)(MF) (MDL 2789)

Dear Judge Cecchi,

Plaintiffs respectfully submit this letter in advance of the November 5, 2018 Status Conference to provide context to the Court for certain items listed in the parties' Joint Status Report and Agenda. As described herein, Plaintiffs request guidance and rulings from the Court to insure that discovery moves forward efficiently and that we will be prepared for trial by September 2020.

Plaintiffs' Requests for Depositions of Defense Witnesses under CMOs 17-20

As the Court is aware, the parties negotiated a document production schedule and "soft caps" on the number of depositions for the AstraZeneca, Takeda, Pfizer/Wyeth, and P&G Defendants. *See* Case Management Orders Nos. 17-20. Throughout that process, the PSC made it clear that it would need to begin depositions in the fall. Indeed, it is necessary to do so in order to prepare expert reports by December 2019, pursuant to Scheduling Order [CMO 21] and given the number of defendants and products implicated in this litigation. With that goal in mind, Plaintiffs served some initial deposition notices on the Takeda and AstraZeneca Defendants on October 18, 2018. These depositions were noticed for November as placeholder dates, with the understanding that the parties would confer on the exact dates and locations for these examinations. While the Takeda Defendant has already provided dates to the PSC, as of the writing of this letter, the AstraZeneca Defendant has failed to do so. Defendants have known for some time that we intended to commence depositions in the fall and the PSC will need to set deposition dates quickly so that the parties can move forward with discovery.

Production of Clinical Documents and Data

This issue relates to the document production from the AstraZeneca Defendants. As the Court may recall, the PSC served their first Request for the Production of Documents in September

26, 2017. Included in this request was a demand for the production of clinical trial documents and data relating to Prilosec and Nexium. Such documents are critical, as they contain significant information relating to the safety and efficacy of the PPIs at issue. In connection with the parties' discovery negotiations and initial 30(b)(6) depositions, AstraZeneca supplied a list of more than 1,500 clinical trials involving Prilosec and/or Nexium. Over the last year, AstraZeneca has made several production of clinical documents and the PSC's understanding was that the clinical data production was to be completed in October 2018.

Unfortunately, after completing a rigorous review of this production and comparing it to the list of clinical trials provided by AstraZeneca, we have found this production to be woefully deficient. Indeed, we are missing information on hundreds of clinical trials that should have been produced—particularly because clinical trial information is usually subject to long-term retention policies and is kept in centralized databases and locations. Nevertheless, cognizant of AstraZeneca's production burdens, we have narrowed the list to certain studies for which we are requesting additional information. On October 24, 2018, we provided AstraZeneca with a list of 83 Prilosec studies for which were missing critical information. Notably, the total list of Prilosec studies identified by Defendant includes approximately 930 studies. An additional 638 Nexium studies have also been identified by AstraZeneca.[1]

Specifically, the additional information sought by Plaintiffs includes clinical study reports for certain trials, as well as case report forms and SAS[2] datasets for select studies. Case Report Forms ("CRFs") are critical in that they are the means by which investigators report and describe adverse events that occur during the course of a clinical trial. It is important for Plaintiffs to review such forms to insure that adverse events relating to kidney injury were not missed and were properly characterized when reported to the FDA and in medical literature. SAS datasets are also very important because analysis of this data is done for safety signal detection, as well as statistical analysis provided to the FDA in support of applications to the Agency for approval to market a prescription drug. SAS data is routinely produced in discovery, pursuant to applicable protective orders, and is needed by Plaintiffs' experts to analyze adverse events across multiple studies or groupings of studies, where appropriate.

As of the writing of this letter, we have not received agreement from AstraZeneca that they will produced the requested information and data. Notably, AstraZeneca has previously represented that it would only be willing to provide SAS datasets *that it provided to the FDA*, rather than all SAS data relating to their PPI products. Such information will be needed for discovery to move forward, particularly as it relates to clinical research and pharmacovigilance witnesses. Plaintiffs need to know if AstraZeneca intends to provide this information and how quickly it can be produced.

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[1] The PSC also prepared a list of Nexium studies for which they are seeking additional information, which was provided to Defendant on November 1, 2018.

[2] "SAS" stands for Statistical Analysis System, which is the primary means by which Defendants' statisticians analyze clinical trial data and other reported adverse events to determine if there are safety signals. The datasets requested are the compilations of data that are analyzed by SAS.

Failure to Provide Adequate Information About the Authors/Recipients of Purportedly Privileged Material

While the PSC continues to meet and confer with several Defendants regarding specific entries on their privilege logs, there remains one disputed issue common to all Defendants with which we have been conferring and for which we now seek the Court's guidance. In the PSC's view, Defendants are failing to provide adequate information about the authors and/or recipients of allegedly privileged material. As a result, Plaintiffs are unable to make an assessment about whether such material has been properly designated or if it should be challenged. This is not a trivial concern. For example, in response to the PSC's challenge of more than 100 entries on one Defendant's privilege logs, that Defendant withdrew the privileged designation on 35 percent of challenged documents. While it is not clear whether that same de-designation rate will apply to other Defendants, the PSC needs adequate information to evaluate whether purported privileged documents have been properly designated.

The Privilege Log Order requires that the log comply with FRCP 26(b)(5) and describe the claimed privilege document to such extent as to enable the parties to assess the claim. While Defendants are providing individual names and which entity (in-house, corporate, outside counsel, etc.) to which that individual belongs, they refuse to provide additional information about the recipient or author of privileged material, such as a job title (current or otherwise) or description of the role that individual plays within the organization. Such information is needed to fairly evaluate the privilege determination. Moreover, such information should already be known to Defendants at the time they make their privilege determination, thus there should be no additional burden in providing this information to Plaintiffs.

Further, there are additional ways in which the limited information provided by Defendants prejudices Plaintiffs' to assess a privilege claim, including:

- Log entries fail to identify the Bates number of the document for which the privilege is claimed and the communication withheld. Bates numbers are required in order for Plaintiffs to evaluate a claim in terms of its environment, particularly the size of the document and family of the documents from which it originated or was transmitted with. *See Medical Technology, Inc. v. Breg, Inc.*, 2010 WL 3734719, *5 (E.D. Pa. Sept. 21, 2010);

- Log entries fail to normalize the identifying information throughout the logs. The "to", "from/author" and "cc" names are provided in varying forms and combinations and one must repeatedly cross-reference and compare entries to one another in order to determine the similarities between the names and if they are indeed the same individual; and

- Log entries fail to identify sufficient employment information for those designated as "legal." In fact, no employment information is provided for attorneys at all. Rather, such individuals are described as simply "legal" or as being in the "attorney nexus." The information lacking includes job title and dates of employment.

FRCP 26(b)(5)(A) imposes the general requirement that a party's privilege log "describe the nature" of the alleged privileged documents and communications withheld or redacted and to "do so in a manner that … will enable other parties to assess the claim." This requirement has been interpreted by various federal courts to require that Defendant identify the following as to each document:

(1) the date of the document;
(2) the full name, job title, and capacity of the author(s) and of each recipient of the document, including all persons carbon copied and blind carbon copied;
(3) the relationship between each recipient(s) and/or author(s);
(4) any other individuals with access to the document and their capacities;
(5) a description of the subject matter of the document with information sufficient to demonstrate the existence of a privilege;
(6) whether the primary purpose(s) of the document was to seek or provide legal advice or services and whether the document was transmitted in confidence;
(7) sufficient information to demonstrate that each element of a privilege is satisfied including a presentation of all factual grounds and legal analyses in a non-conclusory fashion; and
(8) the Bates numbers of the withheld documents.

See Rhone-Poulenc Rorer, Inc. v. Home Indem. Co., 32 F.3d 851, 862 (3d Cir. 1994); *see also In re Grand Jury Investigation*, 599 F.2d 1224, 1233 (3d Cir. 1979); *Medical Technology, Inc. v. Breg, Inc*., 2010 WL 3734719, *5 (E.D. Pa. Sept. 21, 2010). In addition, paragraph B(3) of the Privilege Log Order sets for certain additional information that must be provided, if available, including Document Title and Subject Line.

Defendants have argued that they have no obligation to provide information beyond what is included in the Privilege Log Order. However, Defendants' refusal to provide the additional information requested significantly impedes Plaintiffs' ability to evaluate these claims of privilege. Indeed, the Takeda Defendants have suggested that Plaintiffs' counsel search produced documents and publicly available information to determine the job titles and responsibilities at individuals listed on the privilege log. However, it is not Plaintiffs' burden to prove material is privileged. Rather, that burden rests with Defendants. Plaintiffs are simply requesting information that is readily available to Defendants and which should have been considered by them before even making their privilege determinations. It should not now be Plaintiffs' responsibility to hunt down the most basic information needed to evaluate a claim of privilege. The burden of establishing that a document is privileged is on the party asserting the privilege. *See Nanticoke Lenni-Lenape Tribal Nation*, 2017 WL 4155368 at *3 (D.N.J. Sept. 19, 2017) *citing Torres v. Kuzniasz*, 936 F. Supp. 1201, 1208 (D.N.J. 1996). *See also In re Grand Jury Investigation*, 918 F.2d 374, 385 n.15 (3d Cir. 1990) (discussing the settled Third Circuit rule that the party invoking privilege "has the burden of proving its existence and applicability"); *Schwarz Pharma., Inc. v. Teva Pharma. USA, Inc*., 2007 WL 2892744, *2 (D.N.J. Sept. 27, 2007).

In order for the attorney-client privilege to apply, a communication must be between a client and his or her attorney for the purpose of obtaining legal advice. Therefore, it is necessary for the party claiming privilege to identify all of the parties to a communication, especially the attorney, if any, to enable Plaintiffs to properly review an asserted privilege. A "proper claim of

privilege requires a specific designation and description of the documents within its scope as well as precise and certain reasons for preserving their confidentiality. Thus, 'it is incumbent upon the one asserting the privilege to make a proper showing that all of the elements of the privilege are present.'" *Greene, Tweed of Delaware v. DuPont Dow Elastomers, LLC,*, 202 F.R.D. 418, 423 (D.N.J. 2001) *quoting Allegheny Ludlum Corp. v. Nippon Steel Corp.*, 1990 WL 9837, *1 (E.D. Pa. Feb.1, 1990).

Without an employer name, employment date information, or a job title or description, Plaintiffs cannot evaluate whether the role being played by the individual named relates to the provision of legal advice or some other potential non-legal purpose. This is information that should be provided under FRCP 26(b)(5) and the descriptions as outlined in the Privilege Log Order and the PSC respectfully requests that the Court order Defendants to include such information on their privilege logs.

We thank the Court for its time and courtesy, and look forward to discussing these issues at next week's conference.

Respectfully submitted,

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cc: All Counsel of Record (via ECF)